

REMARKS

Claims 1-77 and 80 are pending in the application. Claims 12, 14, and 73-76 are amended. Claims 12 and 14 are amended for clarity and claims 73-76 are amended to correcting their dependencies. New claim 80 is supported by the original specification, for example, page 19, line 27 to page 20, line 8. Therefore, no new matter has been added. Claims 78-79 are withdrawn by the examiner. The office action is discussed below:

Indefiniteness Rejections:

On page 2 of the office action, the examiner has rejected claims 12 and 14 for using the phrase "or the like." In response, applicants amend the claims by deleting the phrase.

The examiner also has rejected claims 73-76 and alleged as being indefinite for insufficient antecedent basis. In response, applicants amend the claims by correcting their dependencies to claim 63.

Withdrawal of the indefiniteness rejections is requested.

Obviousness Rejections:

On pages 3-8 of the office action, the examiner has rejected claims 1-77 as being unpatentable over Lidgren *et al.* (US 6,448,315) in view of Hahn (US 5,827,904) and further in view of Parth *et al.* (2002), and/or Burstein *et al.* (US 6,629,198), and/or Ylanen *et al.* (US 6,517,857).

Applicants respectfully disagree on all of the above obviousness rejections, because the examiner has failed to establish a *prima facie* case of obviousness.

To establish a *prima facie* case of obviousness, three criteria must be met. First, there must be some motivation or suggestion to make the proposed combination or modification of the references. Second, there must be a reasonable expectation of success. Further, "the teaching or suggestion to make the claimed combination must be found in the prior art, and not based on the applicant's disclosure." MPEP 2142 (Rev. 2, May 2004), discussing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). In addition, the combined, or modified, references must teach or suggest all claim limitations. See also MPEP §§ 2143-2143.03 (Rev. 2, May 2004). Applicants submit that the rejections do not meet this test.

According to the examiner, Lidgren discloses a process for making a medical implant by mixing UHMWPE powder with vitamin E to reduce oxidation, irradiating the mixture with radiation, compression molding the irradiated mixture into the medical implant or machining an implant from compression molded blocks of the irradiated mixture, packaging and sterilizing the implant (referred to Lidgren col. 4, line 45 to col. 5 line 10, and col. 5 line 66 to col. 6, line 8). The examiner states that Lidgren does not teach doping of a consolidated polymeric materials with an antioxidant, however, believes that a combination with Hahn's disclosure would make the claimed invention obvious. Applicants disagree with the examiner and submit that:

Lidgren added an antioxidant to UHMWPE "to reduce oxidation of the polymer during sterilization and post sterilization" (See Lidgren, for example, col. 4, lines 15-20). Hahn doped carotenoid "into powder base or stock solid polymeric material to produce a stable oxidation resistant matrix" (See Hahn, for example, Abstract). Unlike the claimed invention, Lidgren and Hahn neither teach nor suggest irradiating UHMWPE to cross-link (for example, by e-beam) prior to doping with an antioxidant in order to improve wear resistance of the UHMWPE. More specifically, cross-linking of consolidated UHMWPE by irradiation (for example, by e-beam), prior to doping with an antioxidant, is not taught or suggested by Lidgren or Hahn. Both Lidgren and Hahn added the antioxidant to polymeric materials for oxidative stability. Moreover, according to Lidgren, Hahn's process would result in difficulties in removal of the organic solvents used in preparing antioxidant doped UHMWPE. Thus, Lidgren leads in a direction divergent from the path that was taken by the applicants and provides no motivation to be combined with Hahn's process. See *In re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1130, 1131 (Fed. Cir. 1994) (stating, "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant"). Therefore, Lidgren in combination with Hahn does not make the inventions according to claims 1-2, 5-19, 21-35, 38-42, 45-49, 52-55, 57, 59-62, 64-72 and 77 obvious.

Regarding claims 1, 34, 41-42, 48-49, 55, 62, 65-67, and 77, Lidgren and Hahn suggest mixing of polyethylene powder with antioxidants, followed by consolidating the antioxidant-powder mix to obtain oxidation-resistant polyethylene. In contrast, the claimed inventions provide methods wherein the consolidated UHMWPE or

compression molded UHMWPE are doped with antioxidant by diffusion. Applicants point out that mixing of the resin powder, flakes, or particles with vitamin E and consolidation thereafter, according to Lidgren, results in changes in color of the polymeric material to yellow (see Lidgren, for example, col. 6, lines 62-64), which also is noted in the instant specification (see specification, for example, page 2, lines 14-16). Thus, the physical property of the end-product of Lidgren process or a process in combination with Hahn would differ from the end-products of the claimed methods.

Regarding claims 5-7, 38-40, 45-47, 52-54, and 59-61, applicants point out that Hahn discloses doping of UHMWPE with an antioxidant and is silent on when the doping is carried out, whereas Lidgren carries out doping prior to irradiation. On the contrary, according to the claimed processes, doping is a post-irradiation step. Applicants also point out that addition of an antioxidant to UHMWPE prior to irradiation can inhibit crosslinking of the UHMWPE during the irradiation. More specifically, irradiation of UHMWPE in absence or in presence of an antioxidant yields different end-products (see Lidgren, for example, col. 6, lines 62-64; see instant specification, for example, page 2, lines 14-16). When the irradiation crosslinking is carried out in presence of an antioxidant, the crosslinking efficiency of the base polymer is markedly reduced and results in a lower crosslink density of the end-products compared to the crosslink density achieved by crosslinking in absence of an antioxidant.

Applicants also point out that even in the absence of radiation crosslinking, mixing of the UHMWPE powder with vitamin E versus doping of a consolidated finished implant by diffusion yield different end-products. One of the reasons, in the case of mixing with UHMWPE powder, vitamin E would be exposed to an elevated temperatures and elevated pressures during the subsequent steps of consolidation (generally above 200°C), which causes degradation of the antioxidant. Doping by diffusion after consolidation prevents the degradation of the antioxidant. In addition to the degradation of the antioxidant, high temperature and high pressure can cause generation of undesirable by-products, which elute out of a medical implant *in vivo*. According to the claimed invention, the UHMWPE is doped with the antioxidant by diffusion, therefore, the antioxidant is not exposed to elevated temperatures during the consolidation process. Thus, the degradation of the antioxidant is avoided.

Regarding independent claims 1, 34 and 77 and the claims dependent thereof, applicants refer to the above arguments and point out that, unlike Lidgren, the

antioxidant-doping is a post-irradiation step. Regarding independent claim 41, 48, 55 and 62 and the claims dependent thereof, applicants also refer to above arguments and point out that, unlike Lidgren, consolidated UHMWPE are doped with an antioxidant by diffusion. Applicants point out that the methods of Lidgren in combination with Hahn does not teach or suggest "all claim limitations" of the independent claims 1, 34, 41, 48, 55, 62, and 77, thus, can not result in the end-products of any of the claimed methods, as described above. Therefore, Lidgren in combination with Hahn does not make the claimed invention obvious.

Parth *et al.* (2002) mentions crosslinking of UHMWPE by electron beam or gamma irradiation (see page 921, left column, lines 2-4); Burstein *et al.* (US 6,629,198) describes compression molding of a polymeric material and a metallic element to form a medical component (see col. 5, lines 1-8); and Ylanen *et al.* (US 6,517,857) discloses a porous textile product made from bioactive glass fibers (see abstract). Applicants do not understand how Parth, Burstein, and Ylanen disclosures, which provide well-known radiation sources, compression molding of polymeric materials, and bioactive glass, respectively, can provide motivation to be combined with Lidgren or Hahn to arrive at the claimed methods, as stated by the examiner. Accordingly, the examiner has not adequately explained the alleged motivation needed to establish a *prima facie* case.

Applicants submit that the combination of Parth, Burstein, or Ylanen with Lidgren and Hahn is nowhere supported by the references or in the common knowledge of the art. Accordingly, the rejection calls to mind the Federal Circuit decision of *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998), where the court explained:

As this court stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); *see also Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements"). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint to defeat the patentability of the claimed invention. Such an approach would be an "illogical and inappropriate process by which to determine patentability." *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventors and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).

Applicants submit that the rejection does not satisfy the strictures of the *Rouffet* decision. The references are not combinable without proscribed hindsight.


In addition, applicants indicate that Parth *et al.* (2002), Burstein *et al.* (US 6,629,198), or Ylanen *et al.* (US 6,517,857) do not rectify the deficiencies of Lidgren and Hahn. Thus, a combination of Lidgren and Hahn with any of the cited references does not make the claimed inventions obvious.

Therefore, withdrawal of the obviousness rejections is solicited.

REQUEST

Applicants submit that the claims 1-77 and 80 are in condition for allowance and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,



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Date

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